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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/916,140	08/21/97	SCOTT	M	SUV-003.04

HM22/0302

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EXAMINER	
SCHNIZER,R	
ART UNIT	**PAPER NUMBER**
1632	7

DATE MAILED: 03/02/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/916,140	Applicant(s) Scott et al.
	Examiner Richard Schnizer	Group Art Unit 1632

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-49* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-49* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-8, 12, 19, 28, and 29, drawn to DNA sequence analysis, classified in class 435, subclass 6.

II. Claims 9, 10, 20, 21, 30, and 31, drawn to protein detection, classified in class 435, subclass 7.1.

III. Claim 11, drawn to a bioassay, classified in class 435, subclass 7.1.

IV. Claims 32-37, drawn to genetically engineered mammalian cells, classified in class 435, subclass 325.

V. Claims 38-48, drawn to a therapeutic treatment with DNA, classified in class 514, subclass 44.

VI. Claim 49, drawn to a therapeutic treatment with an unidentified agent, classified in class 514, subclass 1.

Claims 13-18, and 22-27 are generic to a plurality of disclosed patentably distinct species comprising groups I and II. If group I or II is elected, claims 13-18, and 22-37 will be examined to the extent that they read on the subject matter of the elected groups.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising groups I, II, and III. If group I, II, or II is selected, claim 1 will be examined to the extent that it reads on the subject matter of the elected groups.

The inventions are distinct each from the other for the following reasons:

The inventions of groups I-III are distinct one from the other because they are each drawn to materially different assays, each of which requires separate and distinct areas of search and consideration. For example, the invention of group I is drawn to DNA sequence analysis which is not required for searches of protein assays (group II) or bioassays (group III). Similarly the bioassay of group III requires search and consideration of *in vivo* effects which is not required for analysis of either group I or group II.

The invention of group IV is related to the inventions of groups I-III because the assays of groups I-III can be used to characterize the cells of group IV. The invention of group IV is distinct from those of groups I-III, because the cells of group I are not required for the practice of the assays of groups I-III, and the search required for group IV is not coextensive with any of the searches required for groups I-III. Further, the assays of groups I-III are not required in order to use the cells of group IV. For example, the cells of group IV can be used to study the phenotype or growth rate of transformed cells without dependence on the assays of groups I-III. On the

other hand, the assays of groups I-III can be practiced on extracts from tissues not containing the cells of group I.

The inventions of groups V and VI are related because they are drawn to therapeutic treatments for animals with loss of function mutations of the *patched* locus. They are distinct because the treatment of group V comprises restoration of *patched* function through administration of a functional expression construct encoding *patched*, whereas, the treatment of group VI alleviates the loss of *patched* function through the administration of an undefined agent which mimics the effect of *patched* on the transcription of genes normally controlled by *patched*-dependent signal transduction. Such an undefined agent may be an antisense oligonucleotide directed against an mRNA whose transcription is normally repressed by the activity of *patched*. In this case, the searches required for the antisense oligonucleotide of group VI would differ from those required for the expression construct of group V.

The inventions of groups I-III are distinct from the inventions of groups V and VI because they are unrelated. The inventions of groups I-III are drawn to assays, whereas the inventions of groups V and VI are drawn to treatments of a genetic disorder. The assays of groups I-III may be practiced independently of the treatments of groups V and VI, and vice versa.

The invention of group IV is related to the inventions of groups V and VI because each invention is drawn toward modifying the function of the signal transduction pathway associated with *patched*. The invention of group IV is distinct from those of groups V and VI because the invention of group IV involves inhibiting the function of *patched*, and can be practiced *in vitro* for the purpose of studying cellular phenotype. The inventions of groups V and VI involve restoring or mimicking *patched* function, and are practiced *in vivo* as treatments for animals suffering a genetic defect. As such, the invention of group IV can be practiced independently of the inventions of groups V and VI, and vice versa.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday-Friday from 7:30 to 4:00 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Stanton, can be reached at 703-308-2801. The FAX phone number for art unit 1632 is 703-308-0294.

Inquiries of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

BRIAN R. STANTON
PRIMARY EXAMINER
GROUP 1800
1600